



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/706,197

11/12/2003

Philip L. Camillocci

132387IT/YOD

5978

7590

06/21/2006

GEMS:0230

EXAMINER

KASZTEJNA, MATTHEW JOHN

Patrick S. Yoder
FLETCHER YODER
P.O. Box 692289
Houston, TX 77269-2289

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP 1

Office Action Summary	Application No. 10/706,197	Applicant(s) CAMILLOCCI ET AL.	
	Examiner Matthew J. Kasztejna	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on March 13, 2006, amended claims 1 and 7 and canceled claim 6 are acknowledged. The current rejections of the claims under 35 USC § 103 *stand*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,380,998 to Kieffer, III et al. in view of U.S. Patent No. 5,514,074 to Yabe et al.

In regards to claims 1 and 7, Kieffer, III et al. disclose a cover having a body 41 having a recessed portion configured to releasably secure to an insertion portion of the endoscope but are silent with respect to a disinfecting compound integral to the body. Yabe et al. teach of an analogous apparatus having an antibacterial agent is coated on the endoscope cover 2A (see Col. 4, Lines 35-40 and Col. 12, Lines 1-6). It would have been obvious to one skilled in the art at the time the invention was made to coat the cover of Kieffer, III et al. with an antibacterial agent to help prevent the growth of unwanted bacteria as taught by Yabe et al.

In regards to claim 2, Kieffer, III et al. disclose a cover, wherein the recessed portion presents a tapered profile with respect to a longitudinal axis thereof.

In regards to claim 3, Kieffer, III et al. disclose a cover, wherein the body comprises an open cell foam as it is disclosed a relatively soft material or the like is used (see Col. 3, Lines 20-45).

In regards to claim 4, Kieffer, III et al. disclose a cover, wherein the body further comprises a channel coupled to the recessed portion such that the channel and recessed portion extend through the body (see Fig. 2).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,380,998 to Kieffer, III et al. in view of U.S. Patent No. 5,514,074 to Yabe et al. in view of U.S. Patent No. 5,458,133 to Yabe et al.

In regards to claim 5, Kieffer, III et al. and Yabe et al. '074 disclose a cover having a body 41 having a recessed portion configured to releasably secure to an insertion portion of the endoscope and a disinfecting compound disposed thereon but are silent with respect to the body including an indicium configured to indicate a contamination condition. Yates et al. '133 teach of an analogous cover for an endoscope wherein an indication device for indicating whether or not an apparatus should handle a clean area in a sterile state or other area is provided on each of the components (see Col. 4, Lines 36-67). Furthermore, Yates et al. '133 teach of using the indicia to help an operator recognize whether he is working with a sterile apparatus or a contaminated apparatus. The indication means for indicating whether an area is a clean or a general area of the cover type endoscope apparatus is not limited to being a

Art Unit: 3739

blue or yellow tape. Rather, in the indication means, colors to be displayed and display areas may be appropriately combined. Also, the indication means is not limited to being a color display, but symbols or characters may be used, or a combination of symbols and characters may be used. It would have been obvious to one skilled in the art at the time the invention was made to apply an indicium to the appropriate covers of Kieffer, III et al. and Yabe et al. '074 in order to allow easy recognition of the contamination status of the apparatus as taught by Yabe et al. '133. The apparatus of Kieffer, III et al. and Yabe et al. is considered to be inherently capable of performing the recited method claims.

Claims 8-13, 15-29, 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,380,998 to Kieffer, III et al. in view of U.S. Patent No. 5,458,133 to Yabe et al.

In regards to claims ~~8~~ 8-13, 15-18, 22-29, 31-36, Kieffer, III et al. disclose a cover having a body 41 having a recessed portion configured to releasably secure to an insertion portion of the endoscope but are silent with respect to the body including an indicium configured to indicate a contamination condition. Yates et al. teach of an analogous cover for an endoscope wherein an indication device for indicating whether or not an apparatus should handle a clean area in a sterile state or other area is provided on each of the components (see Col. 4, Lines 36-67). Furthermore, Yates et al. teach of using the indicia to help an operator recognize whether he is working with a sterile apparatus or a contaminated apparatus. The indication means for indicating whether an area is a clean or a general area of the cover type endoscope apparatus is

m/6/15/20

Art Unit: 3739

not limited to being a blue or yellow tape. Rather, in the indication means, colors to be displayed and display areas may be appropriately combined. Also, the indication means is not limited to being a color display, but symbols or characters may be used, or a combination of symbols and characters may be used. It would have been obvious to one skilled in the art at the time the invention was made to apply an indicium to the appropriate covers of Kieffer, III et al. in order to allow easy recognition of the contamination status of the apparatus as taught by Yabe et al. The apparatus of Kieffer, III et al. and Yabe et al. is considered to be inherently capable of performing the recited method claims.

In regards to claims 19-21 and 37-40, Kieffer, III et al. disclose a cover wherein the first and second cover members comprise an impact absorbing material and may comprise an open cell foam or plastic material (see Col. 3, Lines 20-68).

Claims 14 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,380,998 to Kieffer, III et al. in view of U.S. Patent No. 5,458,133 to Yabe et al. in further view of U.S. Patent Application Publication No. 2002/0013510 to Moriyama.

In regards to claims 14 and 30, Kieffer, III et al. and Yabe et al. disclose a cover having a body 41 having a recessed portion configured to releasably secure to an insertion portion of the endoscope but are silent with respect to the body including an indicium having a raised surface with respect to the body. Moriyama teach of an analogous apparatus wherein an identification part is used to determine if an instrument is suitable for sterilization. Furthermore, Moriyama teach the indicium capable of being

Art Unit: 3739

identified by seeing or touching from any direction. It would have been obvious to one skilled in the art at the time the invention was made to include a raised surface as the indium in the apparatus of Kieffer, III et al. and Yabe et al. to provide the operator tactile feedback as taught by Moriyama.

Response to Arguments

Applicant's arguments filed March 13, 2006 have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., where or not the cover is used during a procedure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As broadly as claimed, Kieffer clearly shows a cover 41 (the removable speculum) for use with an endoscope 20 (see Fig. 2). The cover of

Art Unit: 3739

Kieffer clearly functions to protect the endoscope both while it is not in use as well as when it is in use.

In response to applicant's argument that Kieffer is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Kieffer teaches of a cover 41 used with an otoscope 20, which is identical to the applicant's endeavor, being in a field of medicine related to internal anatomical cavities, some of which may include internal organs and tissues. According to the definition of an otoscope (<http://dictionary.reference.com/browse/otoscope>), an otoscope is an instrument for examining the *interior* of the ear, especially the eardrum, consisting essentially of a magnifying lens and a light. Thus, an otoscope is in fact an endoscope by definition and is analogous art as it clearly is an instrument used in the field of internal medicine.

Furthermore, applicant states that Yabe et al. fail to disclose covers having different indicia representative of different conditions. However, Yabe et al. teaches that a tape, for example, a blue colored tape 30B for indicating a clean area is affixed on an insertion portion cover 3a of the cover 3 which is regarded as a clean area of the cover type endoscope apparatus 1, an operation portion cover 3b and a universal cord cover 3c. A tape, for example, a yellow colored tape 30Y, for indicating a general area is affixed on the covered endoscope 4, a connection cable 47a, a connection cable

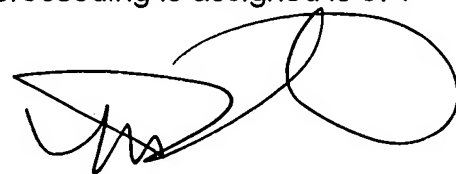
Art Unit: 3739

connector 47b, an extension tube 10a, a cover holder 6, the connector 47 for a universal cord or the like, all of the foregoing are regarded as general areas (see Col. 4, Lines 36-45). Applicant also states that a user would not be able to determine if a part is contaminated or not by viewing the labels of Yabe et al. Yabe et al. clearly discloses that since the blue tape 30B is affixed on the indication means 30 to indicate a clean area and a yellow tape 30Y is affixed thereon to indicate a general area as described above, a person in charge can easily recognize whether an area is a clean or a general area (see Col. 4, Lines 46-51). As broadly as claimed, Yabe et al. disclose first and second cover members comprising first and second indicia, respectively, indicative of the endoscope condition and more specifically as to whether the area is clean or not.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJK



6/13/6



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700